USP <797> Tells You What. Where Do You Go for the How?

If you work in sterile compounding, USP <797> is probably one of the most frequently referenced documents in your pharmacy. It establishes minimum standards for compounded sterile preparations and addresses the major components of sterile compounding, from facilities and engineering controls to personnel qualification, environmental monitoring, cleaning, and beyond-use dating.



But there is an important distinction that sterile compounding teams sometimes overlook:

A standard tells you what is expected. It doesn't always give you every detail you need to build the best possible program.

That is where other chapters, standards, application guides, professional organizations, and regulatory documents become incredibly valuable.

Don't Stop at USP <797>

Think of USP <797> as one part of a much larger sterile compounding library.

Depending on what your pharmacy does, that library may include other applicable USP chapters as

well. It may also include documents from CETA, ASHP, ISO, PDA, FDA, equipment manufacturers, state boards of pharmacy, accreditation organizations, and other authoritative sources.

The goal isn't to accumulate documents. The goal is to know where to look when <797> tells you what must occur, but you need more information to determine how to do it well.

CETA: Turning Requirements Into Practice

CETAs application guides take topics that sterile compounding professionals encounter every day and explore them at a much more practical level. A few applicable CETA guides include:

- CAG-003: Certification of Sterile Compounding Facilities for USP Compliance
- CAG-009: Viable Environmental Monitoring for Sterile Compounding Facilities
- CAG-011: Gloved Fingertip Testing for Sterile Compounding Personnel
- CAG-013: Media Fill Testing for Sterile Compounding Personnel
- CAG-014: Airflow Visualization Study
- CAG-015: Testing of Pass-Throughs

For pharmacies, these documents can help bridge the gap between reading a requirement and understanding how that requirement translates into actual controlled-environment practices.

ISO: Understanding the Environment Itself

When <797> discusses ISO-classified environments, understanding the underlying ISO framework is valuable. ISO 14644-1 addresses classification of air cleanliness by airborne particle concentration and includes principles around classification, testing, evaluation, and reporting. That's a different level of information from simply knowing that an area must meet a particular ISO classification. Especially when reviewing certification results or discussing facility performance with a certifier, understanding the standards behind those tests can make the conversation far more meaningful.

ASHP: Connecting Standards With Pharmacy Practice

ASHP provides another important layer because its resources are developed specifically around pharmacy practice. Its Compounding Resource Center includes resources related to USP <797> changes, designated-person responsibilities, SOPs, hazardous drugs, quality assurance, outsourcing, environmental monitoring, competency assessment, and more.

That makes resources from professional organizations especially useful when pharmacy leaders need to translate technical requirements into day-to-day operations, policies, education, and quality systems.

PDA: Taking a Deeper Dive Into Aseptic Manufacturing and Microbiology

For microbiology and environmental monitoring programs, pharmaceutical-industry guidance can add another level of depth. PDA Technical Report No. 13, *Fundamentals of an Environmental Monitoring Program*, for example, addresses environmental classification, qualification, risk-based sample-site selection, alert and action levels, trending, data management, interpretation, and rapid microbiological methods.

Does every pharmacy operate like a pharmaceutical manufacturer? Of course not. But there is tremendous value in understanding how mature contamination-control programs approach environmental monitoring. You can learn from these principles and determine which concepts make sense for the risk and complexity of your own operation.

FDA: Learn From What Investigators Actually See

Guidance and standards tell one side of the story. Regulatory observations tell another. FDA's *Insanitary Conditions at Compounding Facilities* guidance provides examples of conditions the agency has observed and explains preventative and corrective considerations. Importantly, the guidance applies the statutory prohibition against insanitary conditions to compounded drugs covered under both sections 503A and 503B. That's valuable information even if an FDA investigator isn't walking into your pharmacy. Reading regulatory guidance with your own operation in mind can help turn someone else's observation into your own preventive action.

And Don't Forget the Rest of USP

USP <797> is the foundation for sterile compounding, but it should not be read in isolation. Other USP chapters provide the scientific and technical details behind environmental monitoring, microbiological testing, method suitability, sterilization, endotoxin control, and finished-product quality. Which chapters apply will depend on the preparations you compound, the testing you perform, and the methods used by your pharmacy or contracted laboratory. Here are a few chapters referenced in USP <797>.

Microbiology and contamination-control chapters

- **USP <71>, Sterility Tests:** describes the compendial sterility test and the controls and method-suitability considerations needed to produce meaningful results.
- **USP <85>, Bacterial Endotoxins Test:** provides the compendial framework for detecting or quantifying bacterial endotoxins in applicable preparations.
- **USP <1116>, Microbiological Control and Monitoring of Aseptic Processing Environments:** adds important context for designing, interpreting, and trending a viable environmental monitoring program.
- **USP <1117>, Microbiological Best Laboratory Practices:** addresses laboratory controls such as media preparation and quality control, equipment, sample handling, documentation, data integrity, and microbiological investigations.
- **USP <1223>, Validation of Alternative Microbiological Methods:** supports the evaluation and validation of noncompendial or alternative microbiological technologies.
- **USP <1229>, Sterilization of Compendial Articles:** introduces the principles of sterilization and points to the related <1229.x> chapters for specific sterilization methods and process controls.

Medication use, product handling, and analytical quality chapters

- **USP <659>, Packaging and Storage Requirements:** defines packaging terminology and storage conditions relevant to active ingredients, excipients, and medical products and helps pharmacies interpret requirements for containers, temperature, protection from environmental conditions, and product storage and distribution.
- **USP <1066>, Physical Environments That Promote Safe Medication Use:** describes environmental and human-factors considerations that support accurate medication use, including workspace design and organization, illumination, sound and noise, interruptions, workflow, and other conditions that can affect staff performance and medication safety.
- **USP <1225>, Validation of Compendial Procedures:** explains the performance characteristics and study design used to demonstrate that an analytical procedure is fit for its intended purpose.

The takeaway is not that every pharmacy must apply every chapter in the same way. It is that the

designated person, microbiology partner, and certifier should understand which chapters govern the work, how those chapters relate to one another, and where to find the scientific detail that USP <797> cannot provide on its own.

Build a Reference Library, Not Just a Compliance Binder

Here's our challenge for the month.

Take one part of your sterile compounding program. Maybe it's viable environmental monitoring, media-fill testing, surface sampling, personnel qualification, cleanroom certification, or investigations.

Start with the governing USP requirement.

Then ask:

What other credible guidance exists that could help us do this better?

Your goal shouldn't be to create more work or blindly apply pharmaceutical manufacturing practices to a pharmacy.

Instead, use authoritative resources to understand the science and best practices behind the requirement. Then build procedures that make sense for your facility, personnel, risks, and patient population.

Because knowing what the chapter says is essential.

Understanding why and how is what turns compliance into a strong contamination-control program.

Parasol Perspective: If your environmental monitoring or personnel competency SOP simply repeats USP language, take another look. Your SOP should ultimately tell your staff how *your organization* will reliably perform the activity.